

VA MEDICAL CENTER, PORTLAND, OR

Medical Center
Memorandum No. 151 – 01**RESPONSIBLE CONDUCT OF RESEARCH AT THE
PORTLAND VA MEDICAL CENTER**

1. PURPOSE: To establish policy and procedures for conducting safe and ethical research at the Portland VA Medical Center (PVAMC) that promotes compliance with federal and VA regulations and human subject rights. This Medical Center Memorandum (MCM) also establishes the Human Research Protection Program (HRPP), a systematic and comprehensive approach by the PVAMC to assure human subjects protection in all research.

2. POLICY:

a. All research conducted at the PVAMC by PVAMC employees (full-time, part-time, consulting and attending, contract and without compensation appointments) on PVAMC time and/or using PVAMC property must receive approval through the Research Service prior to being conducted. This may include approval from appropriate Research & Development (R&D) Committee subcommittees: either of the two Institutional Review Boards (IRBs human studies), Institutional Animal Care & Use Committee (IACUC animal studies), and Subcommittee on Research Safety (SRS biohazards/radiation studies).

b. Research is defined by the VA as “the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.” The Common Rule ([38 CFR 16](#) and [45 CFR 46.102](#)) defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.”

c. The ethical conduct of research is a shared responsibility among all individuals involved in research at the PVAMC whether it be human, animal, or basic. It requires cooperation, collaboration, and trust among all institutional representatives, investigators and their staff, the subjects who enroll in the research, members of the IRB, IACUC, SRS, Space Committee and R&D Committee, and R&D Service staff.

d. The PVAMC is engaged in human research when an investigator involves human subjects as defined in the Common Rule in research: “a living individual from whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information.

More complete information is available in the IRB Standard Operating Procedures (SOP) and other Human Research Protection Program (HRPP) policies:

<http://www.visn20.med.va.gov/portland/research/hrpp/index.htm#policies>

e. The HRPP abides by the ethical principles governing research involving human subjects, which are provided in the [Nuremberg Code](#), the [Declaration of Helsinki](#), and the [Belmont Report](#).

(1) The HRPP is additionally governed by the Federal Policy for the Protection of Human Subjects (The Common Rule, Department of Health & Human Services (DHHS) regulations at Title 45 Code of Federal Regulations (CFR) Part 46), codified by the Department of Veterans Affairs at [38 CFR 16](#). In addition, the institution adheres to the Food & Drug Administration (FDA) regulations at [21 CFR 50](#), [56](#), [312](#), [361](#) and [812](#); Department of Defense (DOD) regulations at [32 CFR 219](#); The Freedom of Information Act (FOIA), Title 5 United States Code (U.S.C.) 552, implemented by [38 CFR 1.550-1.559](#); The Privacy Act, 5 U.S.C. 552a implemented by [38 CFR Section 1.575-1.584](#); The VA Claims Confidentiality Statute, 38 U.S.C. 5701, implemented by [38 CFR Section 1.500-1.527](#); Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Human Immunodeficiency Virus (HIV) Infection, and Sickle Cell Anemia Medical Records, 38 U.S.C. 7332, implemented by [38 CFR Section 1.460-1.496](#); the Health Insurance Portability and Accountability Act (HIPAA) (Public Law (Pub. L.) 104-191) implemented by [45 CFR Parts 160 and 164](#); Confidentiality of Healthcare Quality Assurance Review Records, 38 U.S.C. 5705 implemented by [38 CFR Section 17.500-17.511](#); and all relevant academic affiliate policies and VA rules and policies set forth in writing in VHA Handbooks [1200.5](#), [6300.3](#) through [6300.7](#) and [1605.1-1605.2](#).

f. The PVAMC distributes information about volunteering in human research to all potential research participants.

3. RESPONSIBILITIES:

a. The **Medical Center Director** is the Federal-wide Assurance Signatory Official, and is responsible for fulfilling all educational requirements mandated by VA Office of Research Oversight (ORO) and OHRP and ensuring compliance with all federal and VA regulations governing research. S/he is accountable for the HRPP including the protection of human research subjects within the facility. The director appoints the chairs and members of the R&D Committee and all subcommittees and reviews and approves all R&D Committee meeting minutes. The director delegates the authority to administer the R&D program to the Associate Chief of Staff/R&D or his/her designees. Such authority also includes ensuring that all members of the R&D Committee, its subcommittees, and

all investigators are appropriately knowledgeable to oversee and conduct research in accordance with all ethical standards and applicable regulations.

b. The **Chief of Staff** (COS) at PVAMC reports to the Medical Center Director and has overall responsibility for all clinical activities under the purview of the PVAMC.

c. The **Associate Chief of Staff for Research & Development** reports to the Director through the COS and is responsible for the following:

- (1) Developing, managing and evaluating policies and procedures that ensure compliance with all state and federal regulations governing research. This includes monitoring changes in state, VA and other federal regulations and policies that relate to human research protection and overseeing all aspects of the HRPP program.
- (2) Acting as liaison between the VHA Office of Research and Development and the institution's R&D Committee and advising the director and VISN 20 leadership on key matters regarding research.
- (3) Implementing the institution's HRPP policy.
- (4) Submitting, implementing, and maintaining an approved FWA through the Medical Center Director and the Office of Research Oversight (ORO) and to the Office of Human Research Protections (OHRP) and registering its IRBs with the OHRP.
- (5) Administering the facility's R&D Programs, including the R&D Committee and applicable subcommittees.
- (6) Managing the finances of the facility's R&D Program.
- (7) Assisting investigators in their efforts to carry out the VA's research mission.
- (8) Developing and implementing needed improvements and ensuring follow-up of actions as appropriate for the purpose of managing risk in the research program.
- (9) Developing and ensuring completion of human, animal, and bio-safety training requirements for research investigators and members of the applicable subcommittees and staff.
- (10) Reviewing, or designating a reviewer for, all sponsor agreements to assure ethical standards and practices in research are upheld.
- (11) Designating the responsibility to the Administrative Officer for R&D to annually assess performance of all R&D staff and provide feedback on their performance.
- (12) Fulfilling all other responsibilities and adhering to the policies and procedures outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.
- (13) Developing and overseeing an outreach program to all potential research participants at PVAMC.

d. The **Research & Development Committee** serves in an advisory capacity to the Medical Center Director through the COS on the professional and administrative aspects

of the research program. The R&D Committee responsibilities can be found in the [R&D Committee SOP](#).

e. The **R&D Committee subcommittees' chairs and members** are responsible for fulfilling all responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP and R&D Committee's and subcommittees' policies and procedures.

f. **Principal Investigators (PI)** must be VA, Without Compensation (WOC), or Intergovernmental Personnel Agreement (IPA) employees. PIs must have the necessary qualifications for the specific research protocol and cannot be in training. Residents, fellows, and students serving internships or externships, even if licensed, may not serve as PIs. Such investigators must be mentored and the mentor carries the responsibilities of, and is designated as, PI. Responsibilities include, but are not limited to, those listed below:

- (1) ensuring the overall ethical conduct of each research study and the functioning of all research employees involved in each study for which they are the designated PI;
- (2) submitting initial and continuing reviews as well as any amendments for each research project to the R&D Service administrative office according to stated deadlines for applicable committees and subcommittees;
- (3) adhering to specific responsibilities detailed in policies and forms applicable to the type of research to be conducted;
<http://www.visn20.med.va.gov/portland/research/index.htm>.
- (4) ensuring that all research proposals submitted for funding, from any source, support the mission of VHA and enhance the quality of health care delivery to Veterans.
- (5) ensuring that publications include the PVAMC in the address of authors, and VA support must be mentioned in a footnote or acknowledgment.
- (6) fulfilling all other responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Committee's and subcommittees' policies and procedures.

g. The **Research & Development Service Administrative Staff** assigned to the various committees and subcommittees are responsible for the following:

- (1) Reviewing research proposal submissions, advising principal investigators about federal, VACO, and local requirements for conducting research, placing research proposals on the appropriate subcommittee agenda, and coordinating the final approval notification by the ACOS/R&D to the investigator.
- (2) Maintaining subcommittee meeting calendars, minutes, membership information, membership education, study documentation and records in accordance with regulatory requirements.
- (3) Assisting principal investigators who receive approval and funding for research projects with recruitment of research personnel, purchase of equipment and supplies, preparation of monthly budget reports, financial projections, training

requirements, and assistance with day-to-day issues of individual research programs.

(4) Tracking the progress of submitted research protocols.

(5) Fulfilling all other responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Service committee's and subcommittees' policies and procedures.

h. The **Research Assurance and Compliance Coordinator (RACC) or the Research Assurance Officer (RAO) reports to** Associate Chief of Staff, R&D and is responsible for the following:

(1) Critically evaluating adherence of the institution, the IRB, and investigators to applicable federal regulations, state laws, local HRPP policies and accreditation standards, which govern human research.

(2) Writing and maintaining local research policies and standard operating procedures (SOPs) for use in the Research Service to assure functioning in accordance with all federal and applicable state regulations.

(3) Working with the coordinators of the IRB, HRPP, IACUC, and SRS to ensure that day-to-day operations match local policy.

(4) Evaluating performance of each IRB member and chair annually, providing written feedback to the IRB member or chair and submitting a report to the R&D Committee. Such evaluation and feedback shall also be provided as needed if performance problems are observed by the RACC/RAO or reported to the RACC/RAO by someone else.

(5) Critically evaluating the impact of the institution's systemic changes on the conduct of human research and providing information as to whether these changes have led to improvements.

(6) Suggesting systemic improvements in the institution's human research efforts that will either increase human research subject safety or improve compliance with applicable federal regulations, state laws and accreditation standards governing the conduct of human research.

(7) Monitoring and assuring appropriate credentialing and appointment of employees engaged in research.

(8) Directing and facilitating the process of applying for and maintaining accreditation of the HRPP.

(9) Advising and teaching PIs and their research teams concerning the ethical conduct of human research, good clinical practice, local policies and procedures, and federal and applicable state regulations.

(10) Reviewing investigator compliance with educational, credentialing, HRPP and IRB requirements.

(11) Fulfilling all other assigned responsibilities and adhering to the policies and procedures as outlined in the appropriate institutional, HRPP, and R&D Committee's and subcommittees' policies and procedures.

i. The **Research Compliance Officer (RCO) reports to** the Medical Center Director and is responsible for the following:

- (1) Auditing, monitoring, and reporting on the conduct of all PVAMC research to assure compliance with all VA and other federal requirements.
- (2) Serving as a local resource for regulations, policies, memoranda, alerts, and other VA and federal requirements related to research compliance.
- (3) Serving as a non-voting member on the IRB, IACUC, SRS, and R&D Committee.
- (4) Providing education to investigators and research staff regarding regulatory and policy requirements.
- (5) Ensuring prompt reporting in accordance with all applicable policies to the Facility Director and Office of Research Oversight. Simultaneous copies are provided to COS, ACOS/R&D, R&D Committee Chair, IRB Chairs, and the Office of Research and Development, as appropriate or required.

4. PROCEDURES:

a. The PVAMC **R&D Committee** Standard Operating Procedures (SOP) is a reference for R&D Committee members, subcommittee members, investigators and R&D Service administrative staff. The R&D Committee SOP details the policies and procedures specifying the functions of the R&D Committee and the regulations and policies governing the R&D Committee in overseeing the functions of its subcommittees. The R&D Committee abides by the HRPP Policies & Procedures and all other PVAMC Research Policies & Procedures.

b. The R&D Committee has charged the PVAMC **Institutional Animal Care and Use Committee (IACUC)** with ensuring compliance with animal research regulations and oversees the IACUC. The IACUC SOP is a reference for all IACUC members, investigators, and administrative personnel working with animal research. The IACUC abides by the procedures and principles of the IACUC Handbook 1200.7 in the review and conduct of research involving animal research subjects.

c. The R&D Committee has charged the PVAMC **Institutional Review Boards (IRB)** with the oversight of all research activities involving the use of human subjects. The PVAMC IRBs shall perform all functions required under [38 CFR 16](#) (Common Rule) for reviewing and approving human research conducted under the auspices of the institution's FWA. This includes, but is not limited to, research supported by the VA, on VA time or conducted at the PVAMC and research involving VA patients as research subjects (hereafter "VA research"). These responsibilities include maintaining the assurances of compliance set forth in the FWA obtained from the OHRP and only approving research involving human research subjects in accordance with all applicable federal requirements in the protection of human research subjects and operations of the IRB. IRB review and approval of VA Research shall be conducted in accordance with [38 CFR 16](#), [45 CFR 46](#) Subparts A through D, [21 CFR 50](#) and [56](#) (where applicable), and all relevant academic affiliate policies and VA rules and policies set forth in writing in handbooks and directives. The [PVAMC IRB Standard Operating Procedures \(SOP\)](#) is a reference for IRB members, coordinators, investigators and other individuals associated with the HRPP. This SOP details the policies and procedures specifying the regulations

and policies governing human subjects' research and the requirements for submitting research proposals for review by the PVAMC IRBs. The IRB abides by the procedures and principles of VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, in the review and conduct of research involving human subjects.

d. The R&D Committee has charged the **Subcommittee on Research Safety (SRS)** with ensuring compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards, and with oversight of all research activities involving safety hazards. The SRS SOP is a reference for all investigators and SRS members and all involved in research at the PVAMC. The SRS adheres to the policies in VHA Handbook 1200.8.

e. The R&D Committee has charged the **Subcommittee on Research Space** with reviewing requests and reports involving research space in addition to assigning research space. The term "research space" refers to all types of space where research is conducted including dry lab space (for programs more dependent on generation, collection and analysis of clinical data), wet lab space (for biomedical experimentation) and any combination or customization of wet or dry lab space to meet the special needs of PVAMC investigators. The Research Service Space Policy details the procedures by which the Subcommittee on Research Space abides.

f. Neither the R&D Committee, nor the Medical Center Director can approve research that has not been approved by all of the appropriate R&D Committee subcommittee(s) of record. The R&D Committee and higher authority may strengthen requirements and/or conditions, or add other modifications to a protocol approved by all appropriate subcommittees.

g. The annual budget for the HRPP is submitted to the R&D Committee for review and approval.

h. Policies governing PVAMC research are initiated by the ACOS/R&D, reviewed and approved/disapproved by the R&D Committee and implemented as appropriate by the subcommittees, R&D Service administrative staff, investigators, and employees of the PVAMC.

i. Subcommittee meeting minutes shall be available to the R&D Committee no later than three weeks after the convened meeting.

j. Principal Investigators must adhere to the applicable procedures for animal or basic research conducted at the PVAMC:

(1) For research projects to be conducted at the PVAMC or at both PVAMC and Oregon Health & Science University (OHSU), submit a PVAMC Proposed Project Questionnaire and other applicable materials based on the type of research with the research proposal and abstract to the R&D Service Office. The submission must be received in a timely manner to allow adequate time for processing the research proposal.

- (2) Research conducted in hospital wards leased by OHSU that does not involve patients currently considered to be PVAMC in-patients must be reviewed and approved according to all applicable policies at OHSU.
 - (3) For research projects to be administered and conducted only at OHSU (no PVAMC patients, work time, space, supplies, or funds will be utilized), no PVAMC paperwork is required.
 - (4) For research projects to be administered by the Portland VA Research Foundation and conducted at the PVAMC and/or OHSU, submit a PVAMC Proposed Project Questionnaire and other applicable materials and submit these items with the research proposal and abstract to the R&D Service Office. The submission must be received in a timely manner to allow adequate time for processing the research proposal.
- k. For **research involving human subjects** at the PVAMC, principal investigators must adhere to the following procedures:
- (1) Complete all required education in the protection of human research participants.
 - (2) Maintain credentials and, if applicable, privileges at the PVAMC appropriate for performing all procedures proposed in all research protocols involving human subjects submitted by the principal investigator. If the principal investigator lacks the requisite credentials and/or privileges, a collaborating VA clinician who is appropriately credentialed and, if applicable, privileged must be listed on the application. The collaborating clinician assumes responsibility for the specific procedures in question.
 - (3) Obtain approval from the PVAMC IRB. As part of the review process, the principal investigator must comply with all requests for information to assess conflicts of interest.
 - (4) Initiate the study only **after** approval by the IRB and notification of approval from the ACOS/R&D.
 - (5) Adhere to all assurances given to the IRB at the time of project approval.
 - (6) Forward to the R&D Service the original signed informed consent form (VA Form 10-1086) for each patient enrolled in the research project for scanning into the patient's electronic medical record. After scanning, an R&D administrative staff member will return the informed consent form to the principal investigator for inclusion in the protocol case history files. The PI will assure a copy of the informed consent is given to the patient, and that the patient initials the original signed consent form acknowledging receipt of said copy.
 - (7) Promptly report any items listed in item G.1. of RR 602 "Ongoing Review" in the IRB Standard Operating Procedures (SOP).
 - (8) Complete annual review forms for continuing approval of ongoing research.
 - (9) Cite PVAMC IRB approval in the methods section of all manuscripts involving human studies at the PVAMC.
 - (10) Fulfill all other responsibilities and adhere to the policies and procedures outlined in the appropriate institutional, HRPP policies and procedures, and the IRB SOP.

- j. For **research involving animal subjects** at the PVAMC, the principal investigator must adhere to the following procedures:
- (1) Obtain approval from the PVAMC IACUC.
 - (2) Complete continuing review forms for approval of ongoing research and indicating research results, changes in protocol, and completion and termination of the research.
 - (3) Cite PVAMC IACUC approval in the methods section of all manuscripts involving animal studies at the PVAMC.
- (4) Complete all applicable education requirements.
- (5) Fulfill all other responsibilities and adhere to the policies and procedures as outlined in the appropriate institutional and R&D Service committees' policies and procedures.
- k. For **research involving biohazards and/or radioactive materials** at the PVAMC, the principal investigator must adhere to the following procedures:
- (1) Obtain approval for all new grant applications from the PVAMC SRS.
 - (2) Complete continuing review forms for approval of ongoing research.
 - (3) Complete an annual self-inspection survey and pass an inspection conducted by a member of the SRS.
 - (4) Obtain an "Authorized Users License" issued by the Radiation Safety Subcommittee and authorizing the use and purchase of isotopes, if applicable.
 - (5) Complete all applicable education requirements.
 - (6) Fulfill all other responsibilities and adhere to the policies and procedures as outlined in the appropriate institutional and R&D Service committees' policies and procedures.

5. REFERENCES:

- a. [VHA Handbook 1200.01](#), The Research and Development (R&D) Committee
- b. [VHA Handbook 1200.05](#), Requirements for the Protection of Human Subjects in Research, [VHA Handbook 1200.7](#), Use of Animals in Research
- c. VHA Handbook 1200.8, [Safety of Personnel Engaged in Research](#)
- d. VHA Handbook 1200.19, [Presentation of Research Results](#)
- e. [VHA Handbook 1605.1](#), - Privacy and Release of Information
- f. [VHA Handbook 1605.2](#), - Minimum Necessary Standard for Protected Health Information
- g. [PVAMC IRB Standard Operating Procedures \(SOP\)](#)
- h. [PVAMC IACUC website](#)
- i. [PVAMC Research Service Space Policy](#)
- j. [PVAMC R&D Committee Standard Operating Procedures](#)
- k. [Nuremberg Code](#)
- l. [Declaration of Helsinki, June 10, 2002](#)
- m. [Belmont Report, April 18, 1979](#)
- n. [21 CFR 50](#) Protection of Human Subjects
- o. [21 CFR 56](#) Institutional Review Boards
- p. [38 CFR 16](#) Protection of Human Subjects

q. [45 CFR 46](#) *Common Rule*

6. CONCURRENCES:

Research Compliance Officer (RCO)

R&D Committee (R&D)

Chief, Human Resources

Chief of Staff (P3CCE)

Deputy Director for Accounting & Finance (P4DD-A&F)

Deputy Director for Patient Care Services (P2DD-PCS)

7. RESCISSIONS: Medical Center Memorandum No. 151-01 dated June 11, 2008

8. FOLLOW-UP RESPONSIBILITY: ACOS Research & Development Service (R&D)

9. REVIEW DATE:

MICHAEL W. FISHER

Acting Director

Distribution: C